

REMARKS

Applicant has carefully reviewed and considered the Office Action mailed on November 17, 2006, and the references cited therewith. In the office action, claims 77-80, 82-86, 88-102, 112, and 113 were rejected under Section 102 as being anticipated by Anderson et al. (USPN 7,031,768). Claims 87 and 103 were rejected under 35 USC § 103(a) as being unpatentable over Anderson et al. (USPN 7,031,768) in view of Sage Jr. et al (USPN 6,584,349). Claims 81, 104-111 were rejected under U.S.C. 103(a) as being unpatentable over Anderson et al. as applied to claims above, and further in view of Avrahami (USPN 6,615,079). Claims 77, 95, 104, 112 are amended, and claims 1-76 are canceled; as a result, claims 77-114 are now pending in this application.

§102 Rejection of the Claims

Claims 77-80, 82-86, 88-102, 112, 113 are rejected under 35 USC § 102(b) as being anticipated by Anderson et al. (USPN 7,031,768). For a reference to anticipate a claim under 35 U.S.C. §102, "each and every element as set forth in the claim [must be] found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987), cited in MPEP §2131. Applicant respectfully requests that each and every element of the claims as amended are not found in the Anderson reference. Accordingly, Applicants invention is not anticipated by the cited prior art.

Anderson does not teach an implantable device for use beneath the skin as is claimed in Applicant's amended claims. Anderson does not teach a biocompatible semipermeable membrane. Anderson also does not teach an insulated conductor or the creation of a current under the stratum corneum layer of the skin. Anderson, and all of the cited references, disclose *transdermal* drug delivery, not *subdermal* drug delivery. The problem with transdermal drug delivery is that the skin is very resistant to the flow of electric current, particularly the uppermost 15 microns of the stratum corneum. Furthermore, the skin prevents the use of certain higher molecular weight drugs or other beneficial agents.

Anderson and the cited references teach a surface application. Anderson discloses a surface patch (see Col. 7, line 2; Col. 11, lines 25-29; and Figures 2 and 3a). Anderson teaches the use of an adhesive (See Col. 7, lines 44-45) which would not work or be safe in a sub surface

application such as Applicant's. Because Anderson is a surface application, there is no mention or teaching that the semipermeable membrane must be bio-compatible. (See paragraphs 48 and 58 of the application.) Anderson also makes not mention of an insulated conductor. Anderson's noninsulated conductor (see Anderson, Col. 7, lines 18-19) would short circuit the system in a subdermal environment where the device is surrounded or immersed in ionic body fluids. Finally, because Anderson's device is for application to the outer surface of the skin, Anderson does not teach the creation of a current beneath the stratum corneum skin layer. Applicant's invention is for subdermal drug delivery, which requires less voltage to move electric current and is a much more efficient way to delivery drugs by iontophoresis.

Anderson also does not teach each and every limitation of claim 112, Anderson does not anticipate this claim. Examiner has not stated how Anderson anticipates claim 112. Anderson does not reference interocular drug delivery devices, the use of a galvanic cell that uses eye fluid to complete a circuit, or a polymer membrane that is semipermeable to water. Anderson does not teach that the membrane has a first surface being adapted to be placed on the subject's conjunctiva to interact with any liquid present thereon and a second surface configured to contain a beneficial agent for delivery to the subject. Anderson teaches an adhesive for securing a patch to the skin. This device would certainly not work for drug delivery to an eye.

Because Anderson fails to disclose each of the limitations of the independent claims, Applicant submits that claims 77-114 are not anticipated by Anderson.

'103 Rejection of the Claims

Claims 87, 103 were rejected under 35 USC § 103(a) as being unpatentable over Anderson et al. (USPN 7,031,768) in view of Sage Jr. et al (USPN 6,584,349). Claims 81, 104-111 are rejected under U.S.C. 103(a) as being unpatentable over Anderson et al. as applied to claims above, and further in view of Avrahami (USPN 6,615,079). For a 103 rejection to be valid, the combination of references must teach each and every limitation of the claims and there must be some suggestion to combine references.

Regarding claims 81, 87, and 103, the combination of references do not teach each and every limitation of these claims for the reasons set forth above. Regarding claims 104-111, none of the prior art references teaches an implantable device. Specifically, none of the reference,

either alone, or in combination, teach implanting at least a portion of said at least one semipermeable membrane beneath a subject's stratum corneum skin layer. Additionally, these references or any combination of the references do not teach completing a circuit between the electrodes capable of transmitting a voltage from said plurality of electrodes and said at least one semipermeable membrane to said body tissues beneath said stratum corneum skin layer. Accordingly, the references do not teach all of the limitation of claim 104 or the claims depending from claim 104.

Additionally, there is no suggestion to combine the references. The surface applications of the cited references would not work in subdermal applications. The structure and function of Applicant's device and cited references are so different that one of ordinary skill in the art would think to combine the cited references for a subdermal application. Accordingly, claims 81, 87, 103, and 104-111 are not obvious in light of the prior art.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (801-978-2186) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 50-358650-3586

Respectfully submitted,

ASHOK V. JOSHI

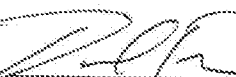
By their Representatives,

801-978-2186

Date

3/19/2007

By



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